AdvaMed
Advanced Medical Technology Association

April 11, 2019

Via Electronic Mail Only
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Opioid Alternative Devices

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide you with information regarding the use of devices as alternatives to opioid use for chronic and acute pain management.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests to treat and manage pain.

In the calendar year (CY) 2019 proposed outpatient prospective payment system (OPPS) rule, the Centers for Medicare and Medicaid Services (CMS) requested comment from stakeholders regarding the impact of OPPS and ambulatory surgical center (ASC) payment policies on the ordering and use of non-opioid alternatives in treating Medicare beneficiaries. AdvaMed's comments noted that medical devices, including ones that provide, and assist in the provision of, effective pain management solutions, have the potential to reduce Medicare beneficiaries' dependence on opioids and help curb opioid misuse, abuse, and overdose. We also encouraged CMS to explore mechanisms that would incent surgical approaches (i.e. minimally invasive surgery) which reduce post-surgical pain and the need for opioids to manage it. AdvaMed's comments also addressed

payment inadequacies for opioid alternative devices which create disincentives to their use.

AdvaMed's comments supported CMS's proposal to pay separately for certain non-opioid pain management therapies in the ASC that demonstrate a reduction in opioid usage through currently available or prospective published evidence. We also commented that CMS can use its equitable adjustment authority under 42 U.S.C. § 1395l(t)(2)(E), and other possible mechanisms, such as add-on payments, to ensure payments under the OPPS are adequate for alternative, non-opioid pain management therapies and other treatment approaches shown to reduce the need for opioids.

While CMS did not finalize any policy changes in this area in the final CY 2019 OPPS rule, there continues to be significant activity and engagement in this area by several interested stakeholders. An inter-agency taskforce convened by the Secretary of Health and Human Services, in cooperation with the Secretary of Defense, and the Secretary of Veterans Affairs recently released a report regarding pain management best practices for patients experiencing acute and chronic pain. Additionally, Congress passed H.R. 6 The SUPPORT for Patients and Communities Act (the SUPPORT Act). Section 6082 of the SUPPORT Act requires CMS to review and revise policies for OPPS payment for non-opioid alternative treatments, including evidence-based non-opioid alternatives for pain management and surgical services assigned to ambulatory payment classifications (APCs).

AdvaMed supports the Federal government's continued efforts to address the opioid crisis that is taking a tremendous toll on our country and its citizens. As CMS continues to address policy changes in this area, we would like to provide comments on a few areas that may be of interest to you. Our comments will cover the following issues:

1. Appropriate Reimbursement
2. Ensuring Access

Appropriate Reimbursement

AdvaMed member companies manufacture a range of technologies that can markedly reduce the need to prescribe opioids to patients experiencing chronic and acute pain. Given the link between opioid abuse and chronic and acute pain, we believe CMS can and should actively support methods to alleviate pain without opioids by implementing appropriate coverage, coding, and reimbursement policies. Non-opioid interventions may include minimally invasive surgery, and other invasive and non-invasive pain management modalities, such as spinal cord stimulators, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, electromagnetic

energy, digital therapeutics, vertebral augmentation, ultrasound guided regional anesthesia, and portable continuous pain relief systems—including elastomeric pumps.

Any payment policy changes should minimize financial burdens to use needed devices by not increasing patient liability. For example, AdvaMed would encourage CMS to consider the use of add-on payments and other mechanisms that will appropriately adjust reimbursement for these devices without increasing patient cost. CMS should also consider implementing policy changes that will create co-pay parity between opioids and device-based alternatives to allow patients and their physicians to choose the best, as opposed to the least expensive, treatment based upon individual need.

The discrepancy between ASC and OPPS beneficiary cost-sharing amounts can also be a barrier to patient access to non-opioid pain management alternatives in the ASC setting, and may lead to lack of care, delay in care, or migration of care from the ASC to other settings. Specifically, the lack of a deductible cap on the ASC coinsurance amount may result in higher patient cost-sharing for certain device-intensive non-opioid pain management alternatives in the ASC setting. While we recognize that the law establishes coinsurance at 20 percent of Medicare's allowance, AdvaMed recommends that CMS work with Congress to remove this barrier to non-opioid pain management alternatives in the ASC setting.

There are a variety of device-based alternatives available to manage acute pain with limited or no opioids (thereby limiting or avoiding the risks of developing opioid use disorder (OUD)). However, disincentives in the Medicare payment system may limit and/or prevent access to these technologies. Specifically, some devices and services used to avoid opioids for acute, post-surgical, pain are currently bundled into the supply or equipment costs for the overall procedure. Consequently, hospitals may have financial disincentives to prescribe/use the device in lieu of prescribing a lower cost and potentially addictive opioid that will be reimbursed under Part D-- even in a patient that may be at risk for OUD. CMS should act to resolve this disparity in patient access to these alternative devices by creating a mechanism for separate payment for device-based opioid alternative supplies, equipment, and guidance procedures that are utilized in in hospital, emergency, and other settings for urgent and acute pain management.

Similarly, there are many devices used to treat patients who experience chronic pain. As CMS evaluates the OPPS payment system, per the directives of Section 6082 of the SUPPORT Act, we would ask that you consider means to ensure that evidence-based non-opioid alternative devices for pain management are not overlooked due to reimbursement concerns. AdvaMed would ask CMS to consider payment system changes that will encourage providers to use these devices when needed without fear of negative financial impacts. We would also suggest that CMS consider other outpatient payment policy changes that will improve utilization of these devices, when needed, such as pass-

through payments and new technology APC assignments. In the case of pass-through designation and new technology APCs, AdvaMed also recommends that CMS modify the qualifying criteria to also include consideration of the ability to avoid use of opioids as a substantial clinical improvement and to reduce the time for processing and approving the designation for these types of technologies.

Ensuring Access

One of the issues that AdvaMed members experience, related to the deployment of opioid alternative devices, is the inability of patients to access these innovations at the appropriate time. These access concerns are the result of various issues including delays in acquiring an appropriate code (e.g. CPT or HCPCS) to identify and track use of the device. Additionally, coverage delays in the form of requirements such as prior authorization or "step therapy", which may require patients to undergo drug therapy for pain relief (posing possible addiction risk) prior to being able to utilize a device-based intervention, are impeding patient access to needed technologies.

To avoid OUD, it is critically important that patients can access alternatives at a time that suits their individual needs—which can vary depending upon family and personal history or other physical and psychological conditions— to avoid the prescription and use of opioids. AdvaMed would encourage CMS to consider recommendations regarding code review and approval processes that recognize the necessity of bringing evidence-based opioid alternative devices to the patients that need them with minimal delay—including new devices and iterative improvements to existing devices. AdvaMed also recommends that coverage policies be modified to accommodate patients who may be at risk of OUD. CMS should provide coverage, payment, and immediate access to device-based treatments that avoid the prescription and use of opioids at the onset of treatment instead of requiring these patients to undergo a step-wise treatment approach that may start with drug therapy.

Conclusion

AdvaMed is supportive of CMS's commitment to reduce inappropriate patient use of opioids by integrating device-based opioid alternative technologies into the health care system so that patients, especially those at risk for OUD, can utilize them as soon as possible. We urge CMS to continue to work with payers and other entities to implement payment system and policy changes that ensure patient access to opioid device alternatives.

We would be pleased to answer any questions regarding these comments. Please contact

DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery

cc: Demetrios Kouzoukas
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